

# CHECK POINTS FOR ALLERGEN INSPECTIONS

WISCONSIN DIVISION OF FOOD SAFETY

## RAW MATERIALS

Suppliers, Receiving and Storage

### Suppliers & Receiving

- Determine if suppliers have allergen control plans
- Obtain a Certificate of Analysis or Guarantee
- Determine if suppliers clearly label any allergen-containing ingredients
- Obtain fully disclosed ingredients lists and routinely verify all lists
- Request prior notification of any change in suppliers' product formulations
- Double-check formulas during scale-up
- Do not purchase reconditioned ingredients or oils
- Ensure that vehicles, pallets, etc. are free from allergen residues

### Storing raw materials

- Use clearly marked storage containers
- Keep allergens separate
- Reserve containers for allergen use only
- Watch for allergenic foreign material
- Ensure that vehicles, pallets, etc. are free from allergen residues
- Use dedicated storage areas for allergens

## PROCESSING

Scheduling, Cross-contamination, Rework and Personnel & Aids

### Proper scheduling

- Make non-allergenic products first
- Run allergen-containing products at the end of the schedule
- Follow non-allergenic products with allergen-containing foods before cleaning for changeover
- Allergen-containing products need to be made in successive batches/runs
- Minimize changeovers by scheduling long runs of allergenic products

### Preventing product cross-contamination

- Establish a specific schedule of procedures for employees (hand-washing after handling peanuts, etc.)
- Rework must go into a batch of the same product
- Do not allow reuse of single service articles such as tray liners.
- Design the product flow so that allergenic ingredients are added at the end
- Protect work-in-process from contamination from other product on adjacent conveyors, etc.
- Consider cross-contamination on packaging equipment

#### Handling rework

- Have a documented rework plan
- Rework “like into like” only
- Clearly identify rework area, equipment, containers, etc.
- Identify allergenic products when reworked
- Track rework to document how it’s eventually used
- Try to use rework within the same run

#### Personnel and Aids

- Consider dedicating personnel to allergen product areas
- Sanitize any sampling instruments or devices between products
- Consider use of cornstarch, lecithin, etc.

### **EQUIPMENT & SANITATION**

#### Equipment use & design

- Dedicate separate equipment, lines, rooms or facilities for allergen-containing product, if possible
- Color-code areas, equipment, containers and/or utensils for allergen use
- Be aware of how equipment design affects potential cross-contamination
- Include any utensils and equipment tools in allergen planning
- Encourage workers to speak up if they see need for changes or improvements

#### Proper sanitation

- Thoroughly clean all equipment and visually inspect it afterwards
- Focus on hard-to-clean areas and look for “hidden” residues
- Inspect the line to make sure it’s “allergen clean”
- Ensure proper storage of clean items
- Allow for appropriate time between changeovers
- Focus on results and be aware that clean-up may require extra effort

- Create a sanitation procedure check-list
- Use of immunoassays may detect allergenic proteins; swabbing equipment may pinpoint the source

## **LABELING & PACKAGING**

### Product Formulation, Content of the Label, and Packaging

#### Product formulation

- Be aware of ingredients that may cause allergic or adverse reactions
  - Label or separate products that cause allergic reactions
  - Verify during scale-up that correct ingredients are used
- Allergen-derived ingredients are edible oils, flavors and hydrolyzed proteins – *no protein, no problem.*
- Use ingredients that are already included in other products
- Avoid using allergenic ingredients in such small amounts that they have no functional effect on the product
- Make NO substitutions unless your label reflects the change

#### Apply accurate labels

- List all ingredients with proper names
- Include sub-ingredients (i.e., list the ingredients of soy sauce)
- List the specific source of vegetable oils and proteins
- Include in the product NO undeclared ingredients
- Color code and change color of packaging for product with new formulation
- Color code and change color of packaging for similar products with different formulations

#### Packaging

- Check for correct packaging material
- Check labels during product run
- Throw out old or out-of-date packaging
- Develop systems to assure individual, unlabeled items (granola bars, etc.) are eventually packaged and labeled properly
- Check for latex use during packaging process

## **LABELING LANGUAGE**

### Plain Language, Required Ingredients, and Supplemental Statements

#### Plain language on labels

Ingredient terms commonly understood by consumers for the major food allergens should be disclosed on the information panel, within, or in the immediate proximity to, the ingredient statement of the food label, by using one or more of the following methods:

- The use of a statement such as, “**Contains \_\_\_\_\_**,” with the blank filled in with the ingredient term commonly understood by consumers for the major food allergens. (e.g. “Contains Soy and Milk”). This statement may be pre-fixed by an allergy information statement phrase (e.g. **Allergy Information: Contains Soy and Milk**).
- The use of an asterisk or other reference mark next to the ingredient name or class name that refers the consumer to a statement that identifies the ingredient term commonly understood by consumers for the major food allergens. Example:..., casein\*, whey\*, semolina†, natural flavor‡,... would appear in the ingredient statement, referring to the consumer statement, such as: “**Allergy Information: Contains \* Milk, and †wheat**”.
- The use within the ingredient statement of a parenthetical statement following the ingredient name or class name that identifies the allergens that are present in the ingredient such as: “..., **natural flavor(peanuts and soy), whey (milk)...**”.
- The use within the ingredient statement of a name that identifies the presence of the allergen such as: “**natural walnut flavor**”, or “**natural peanut flavor**.”
- The use of bolding or highlighting within the ingredient statement, or in allergy information statements, in immediate proximity to the ingredient declaration.

#### Required ingredient labeling

Ingredients required to be declared on the label, must be listed by their common or usual name in descending order of predominance by weight. **Source: 21CFR 101.4 (a)**

An complex ingredient which itself contains two or more ingredients, must be declared in the ingredient statement by:

- Declaring the common or usual name of the multi-component food, followed by a parenthetical listing of each ingredient in descending order of predominance.
- Declaring each ingredient in the multi-component food in descending order of predominance without listing the ingredient itself.
- If the term “salad dressing” appears on the label ingredient declaration; then each sub-ingredient must be listed.
- If the term “soy sauce” appears on the label ingredient declaration; then each sub-ingredient must be listed. **Source: 21CFR 101.4 (b) (1)**

Each individual ingredient of a food intended for consumption shall be declared by its common or usual name, for example:

- If the term “yolk” appears on the label ingredient declaration and in fact it is “egg yolk”; then it must be labeled as “egg yolk”. **Source: 21 CFR 101.4 (b)**
- If the term “nondairy” appears on the label ingredient declaration then it must be followed by a parenthetical statement identifying it’s source (e.g. ...,casein(a milk derivative) **Source: 21 CFR101.4 (d)**

#### Supplemental labeling statements

Food processors that prepare food potentially exposed to inadvertent contact with major food allergens acknowledge that labeling is not a substitute for good manufacturing practices (GMP). Supplemental labeling statements are used when the ingredient is not present in the product, but risk of contamination is present even when the firm is using Good Manufacturing Practices.

**Supplemental allergen statements should be used judiciously and only when all four of the following criteria are met:**

- 1) The presence of the Major Food Allergens is documented through visual examination or analytical testing of the processing line, equipment, ingredient or product, or other means;
- 2) The risk of the presence of the Major Food Allergens is **unavoidable** even when current GMP’s are followed.
- 3) A Major Food Allergen is present in some, but not all, of the product; and,
- 4) The presence of a Major Food Allergen is potentially hazardous.

**When all four of these criteria are satisfied, the supplemental allergen statement should be placed, at the end of, or in close proximity to the ingredient statement.**

Some examples are “May Contain (allergen),” and “This product was processed on machinery that was used to process products containing (allergen)”.